DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2022-0116]

CDC Recommendations for Hepatitis C Testing Among Perinatally Exposed Infants and Children—United States, 2023; Request for Comment and Notice of Informational Webinar

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on proposed new recommendations for perinatal hepatitis C virus (HCV) infection testing to identify infants who may go on to develop chronic hepatitis C. Recommendations include: HCV testing of all perinatally exposed infants at age 2-6 months with a Nucleic Acid Test (NAT) for detection of HCV ribonucleic acid (RNA); and referral of infants with detectable HCV RNA to a healthcare provider with expertise in pediatric hepatitis C management. CDC also announces an

Informational Webinar to explain the public comment process.

DATES: Written comments must be received on or before January 27, 2023.

The Informational Webinar will be held December 6, 2022 from 3–4 p.m. EST.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0116 by either of the methods listed below.

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Division of Viral Hepatitis, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop U12–3, Atlanta, GA 30329, Attn: Docket No. CDC–2022–0116.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to https://www.regulations.gov, including any personal information provided. **Do not submit comments by email; CDC does not accept comments by email.** For access to the docket to read background documents or comments received, go to https://www.regulations.gov.

Registration for Informational Webinar: You can register for the webinar at https://www.zoomgov.com/webinar/register/WN_tDK5btj3QpGcmDzKVjvDbw. **CDC will not accept public comment during this webinar.**

FOR FURTHER INFORMATION CONTACT: Lakshmi Panagiotakopoulos, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop U12-3, Atlanta, GA 30329. Email: DVHpolicy@cdc.gov. Telephone: (404) 639-8000.

SUPPLEMENTARY INFORMATION:

Background

Hepatitis C virus (HCV) infection is the most commonly reported blood-borne infection in the United States, causing substantial liver damage and death.[1] During 2017-2020, there were an estimated 2.2 million non-institutionalized adults in the United States living with hepatitis C.[2] Percutaneous exposure (e.g., injection drug

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[1] Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report—United States, 2020. https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm. Published September 2022. *See also* Hofmeister, M.G., Rosenthal, E.M., Barker, L.K., Rosenberg, E.S., Barranco, M.A., Hall, E.W., Edlin, B.R., Mermin, J., Ward, J.W. and Ryerson, A.B. (2019), Estimating Prevalence of Hepatitis C Virus Infection in the United States, 2013-2016. Hepatology, 69: 1020-1031. https://doi.org/10.1002/hep.30297 Rosenberg ES, Rosenthal EM, Hall EW, Barker L, Hofmeister MG, Sullivan PS, Dietz P, Mermin J, Ryerson AB. Prevalence of Hepatitis C Virus Infection in US States and the District of Columbia, 2013 to 2016. JAMA Netw Open. 2018 Dec 7;1(8):e186371. doi: 10.1001/jamanetworkopen.2018.6371. PMID: 30646319; PMCID: PMC6324373.

[2] Thompson WW, Symum H, Sandul A, et al. Vital Signs: Hepatitis C Treatment Among Insured Adults—United States, 2019-2020. MMWR Morb

use or blood transfusion) is the most efficient mode of HCV transmission, and injection drug use is the primary risk factor for infection.[3] National surveillance data reveal a steady increase in HCV infections in the United States from 2010 through 2020, with rates of acute infections more than quadrupling among reproductive aged persons during this time, corresponding with increases in injection drug use.[4] Approximately 7 percent of perinatally exposed children (i.e., those coming into contact with the virus during pregnancy or delivery) will acquire perinatal HCV infection.[5] Curative direct-acting antiviral (DAA) drugs are an FDA-approved treatment, currently approved for use beginning at 3 years of age. However, many perinatally infected children are not tested or linked to care.[6,7,8,9]

Mortal Wkly Rep 2022;71:1011-1017. DOI: http://dx.doi.org/10.15585/mmwr.mm7132e1

[3] Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report—United States, 2020. https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm. Published September 2022.

[4] Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report—United States, 2020. https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm. Published September 2022.

[5] Benova, L., et al., Vertical transmission of hepatitis C virus: systematic review and meta-analysis. Clin Infect Dis, 2014. 59(6): p. 765-73.

[6] Towers, C.V. and K.B. Fortner, Infant follow-up postdelivery from a hepatitis C viral load positive mother. J Matern Fetal Neonatal Med, 2019. 32(19): p. 3303-3305.

[7] Lopata, S.M., et al., Hepatitis C Testing Among Perinatally Exposed Infants. Pediatrics, 2020. 145(3).

[8] Hojat, L.S., et al., Using Preventive Health Alerts in the Electronic Health Record Improves Hepatitis C Virus Testing Among Infants Perinatally Exposed to Hepatitis C. Pediatr Infect Dis J, 2020. 39(10): p. 920-924.

[9] Kuncio, D.E., et al., Failure to Test and Identify Perinatally Infected Children Born to Hepatitis C Virus-Infected Women. Clin Infect Dis, 2016. 62(8): p. 980-5.

The World Health Organization (WHO)'s global health sector strategies[10] for eliminating viral hepatitis include diagnosing at least 90% of people living with hepatitis C by 2030. In support of this goal, CDC conducted a systematic review of the literature to develop recommendations for testing perinatally exposed infants and children for hepatitis C. Among children born to women with HCV infection, well-child visits in the first 6 months of life are the most frequently attended and provide an opportunity to test in a patient group that is often lost to follow-up. Although treatment is not currently approved for infants and children under 3 years of age, it is important to test exposed infants as close to birth as possible and record a diagnosis in the medical record. HCV-infected infants and children are usually asymptomatic, and it is important to diagnose and treat HCV infection before liver damage occurs. Prior studies have estimated that, in the United States, the total annual burden of HCV infection was about 10 billion U.S. dollars in 2017.[11] Proper identification of perinatally infected children, referral to care for evaluation and monitoring, and curative DAA

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[10] Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030. Geneva: World Health Organization; 2022. License: CC BY-NC-SA 3.0 IGO. Available at: https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/strategies/global-health-sector-strategies

[11] Stepanova M, Younossi ZM. Economic Burden of Hepatitis C Infection. Clin Liver Dis. 2017 Aug;21(3):579-594. doi: 10.1016/j.cld.2017.03.012. Epub 2017 Apr 22. PMID: 28689595.

treatment are critical to achieving the goal of hepatitis C elimination.

As described in the recommendation document found in the Supporting and Related Materials tab of the docket, these recommendations supplement "CDC Recommendations for Hepatitis C Screening Among Adults—United States, 2020," which includes screening during each pregnancy, by recommending the timing and type of HCV test for infants and children born to persons determined to have HCV infection in pregnancy. In addition, this recommendation replaces a prior recommendation for testing perinatally exposed infants and children included in a CDC guideline from 1998,[12] as HCV epidemiology and methods of testing infants and children for HCV infection have evolved.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data related to any of the proposed recommendations or supporting evidence. In addition, CDC invites comments specifically on the following questions:

- Based on the evidence presented in the full recommendations document (*see* Supporting and Related

[12] Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. Centers for Disease Control and Prevention. MMWR Recomm Rep. 1998 Oct 16;47(RR-19):1-39. PMID: 9790221.

Materials tab), does the evidence support the proposed recommendations for testing perinatally exposed infants and children for HCV infection? If not, please state the reason why and, if available, provide additional evidence for consideration.

- Are CDC's proposed recommendations (*see* Supporting and Related Materials tab) clearly written? If not, please provide changes to make them clearer.
- If implemented as currently drafted, do you believe the proposed recommendations would result in increased identification and treatment of perinatal HCV infections and reduction in associated health and financial consequences in the United States (e.g., healthcare costs to treat complications of chronic hepatitis C)? If not, please provide an explanation.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on https://www.regulations.gov. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on

public display. CDC will review all submissions and may choose to redact or withhold submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate or near duplicate examples of a mass-mail campaign.

Informational Webinar: CDC will host an Informational Webinar on December 6, 2022 from 3:00–4:00 p.m. EST to explain the public comment process. **CDC will not accept public comment on the Draft Recommendations during the webinar.**

Dated: November 17, 2022.

Angela K. Oliver,

Executive Secretary,

Centers for Disease Control and Prevention.

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